(iv) A warning about staying alert to sounds around the user of the device;

(v) Technical information about the device, including information about EMC; and

(vi) Information on how to correctly use and maintain the device.

[84 FR 57612, Oct. 28, 2019]

§ 874.3330 Master hearing aid.

(a) *Identification.* A master hearing aid is an electronic device intended to simulate a hearing aid during audiometric testing. It has adjustable acoustic output levels, such as those for gain, output, and frequency response. The device is used to select and adjust a person's wearable hearing aid.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

[51 FR 40389, Nov. 6, 1986, as amended at 84 FR 71813, Dec. 30, 2019]

§ 874.3340 Active implantable bone conduction hearing system.

(a) *Identification.* An active implantable bone conduction hearing system is a prescription device consisting of an implanted transducer, implanted electronics components, and an audio processor. The active implantable bone conduction hearing system is intended to compensate for conductive or mixed hearing losses by conveying amplified acoustic signals to the cochlea via mechanical vibrations on the skull bone.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must characterize any adverse events observed during implantation and clinical use, and must also demonstrate that the device performs as intended under anticipated conditions of use.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including the following:

(i) Performance data must validate force output in a clinically relevant model.

(ii) Impact testing in a clinically relevant anatomic model must be performed.

(iii) Mechanical integrity testing must be performed.

(iv) Reliability testing consistent with expected device life must be performed.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the patient-contacting components of the device.

(5) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(6) Performance data must demonstrate the wireless compatibility, electromagnetic compatibility, and electrical safety of the device.

(7) Software verification, validation, and hazard analysis must be performed.

(8) Labeling must include:

(i) A summary of clinical testing conducted with the device that includes a summary of device-related complications and adverse events;

(ii) Instructions for use;

(iii) A surgical guide for implantation, which includes instructions for imaging to assess bone dimensions;

(iv) A shelf life, for device components provided sterile;

(v) A patient identification card; and

(vi) A patient user manual.

[83 FR 54009, Oct. 26, 2018]

§ 874.3375 Battery-powered artificial larynx.

(a) *Identification.* A battery-powered artificial larynx is an externally applied device intended for use in the absence of the larynx to produce sound. When held against the skin in the area of the voicebox, the device generates mechanical vibrations which resonate in the oral and nasal cavities and can be modulated by the tongue and lips in a normal manner, thereby allowing the production of speech.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in